AMENDMENT TO
RULES COMMITTEE PRINT 118–10
OFFERED BY MS. DELAURO OF CONNECTICUT

Add at the end of title XVIII the following:

SEC. _____. PROHIBITING ACQUISITION OF OR PAYMENT FOR PHARMACEUTICALS NOT MANUFACTURED IN FACILITIES IN COMPLIANCE WITH FEDERAL STANDARDS.

(a) PROHIBITION.—

(1) IN GENERAL.—The Secretary of Defense may not purchase or otherwise obtain, and may not include on the uniform formulary of pharmaceutical agents under the pharmacy benefits program established under section 1074g of title 10, United States Code, any pharmaceutical agent which is manufactured, or for which any of its active pharmaceutical ingredients is manufactured, in a facility which is not a certified facility.

(2) EXCEPTIONS.—Paragraph (1) does not apply with respect to a pharmaceutical agent if—

(A) the Secretary, in consultation with the Director of the Food and Drug Administration, finds that the agent is not available from cer-

tified facilities in sufficient quantities to meet the needs of the Secretary; or

(B) the agent, or any of its active pharmaceutical ingredients which is not manufactured in a certified facility, has been tested and certified as safe by an accredited independent laboratory which tests pharmaceutical agents and their active pharmaceutical ingredients and certifies their safety, but only if the testing is based on samples obtained by the laboratory from a source other than the manufacturer of the agent or its ingredient.

(b) INVESTIGATION AND REPORT ON SAFETY OF CHINESE FACILITIES.—

(1) INVESTIGATION.—The Director of the Food and Drug Administration shall conduct an investigation to determine whether facilities in the People's Republic of China which manufacture pharmaceutical agents and their active pharmaceutical ingredients, as regulated by the Food and Drug Administration, meet the same health and safety standards required of facilities in the United States.

(2) REPORT TO CONGRESS.—Not later than 6 months after the date of the enactment of this Act,

the Director of the Food and Drug Administration—

(A) shall certify to Congress that, on the basis of the investigation conducted under paragraph (1), facilities in the People's Republic of China which manufacture pharmaceutical agents and their active pharmaceutical ingredients meet health and safety standards which are substantially the same as the standards met by facilities in the United States; or

(B) submit a report to Congress on a plan for protecting individuals who use pharmaceutical agents provided by or paid for by the Secretary of Defense from unsafe or contaminated agents manufactured in the People's Republic of China.

(c) DEFINITIONS.—In this section, the following definitions apply:

(1) ACCREDITED INDEPENDENT LABORATORY.—The term ''accredited independent laboratory'' means a facility accredited to ISO 17025 or equivalent standards and not accredited to cGMP to ensure no conflicts of interest and whose accreditation is current and in compliance with an appropriate accreditation body for the testing of pharma-

ceutical agents and their active pharmaceutical ingredients.

(2) ACTIVE PHARMACEUTICAL INGREDIENT.—The term ''active pharmaceutical ingredient'' has the meaning given such term in section 207.1 of title 21, Code of Federal Regulations, or any successor regulation promulgated by the Director of the Food and Drug Administration.

(3) CERTIFIED FACILITY DEFINED.—The term ''certified facility'' means a facility which the Director of the Food and Drug Administration certifies, on the basis of an on-site inspection conducted by the Food and Drug Administration, to be in compliance with all applicable health and safety standards of the Food and Drug Administration for facilities engaged in the manufacture of pharmaceutical agents and their active pharmaceutical ingredients, including standards requiring active and ongoing monitoring and testing of such agents and their active pharmaceutical ingredients.

(4) PHARMACEUTICAL AGENT DEFINED.—The term ''pharmaceutical agent'' means drugs, biological products, and medical devices under the regu-

latory authority of the Food and Drug Administration.

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